



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2020-0424; FRL-9063-01-OCSP]

Isoprothiolane; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of isoprothiolane in or on banana; rice, bran; rice, husked; and rice, polished rice. Nichino America, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2020-0424, is available at <https://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to

provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Office of the Federal Register's e-CFR site at <https://www.ecfr.gov/current/title-40>.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in

40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2020-0424 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2020-0424, by one of the following methods:

- *Federal eRulemaking Portal*: <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <https://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the *Federal Register* of December 21, 2020 (85 FR 82998) (FRL-10016-93), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9E8820) by Nichino America, Inc., 4550 Linden Hill Road, Suite 501, Wilmington, DE 19808. The petition requested that 40 CFR part 180 be amended by

establishing tolerances for residues of the fungicide isoprothiolane, Diisopropyl 1,3-dithiolan-2-ylidenemalonate, in or on raw agricultural commodities banana at 1 part per million (ppm); rice, bran, at 30 ppm; rice, husked, at 6 ppm; and rice, polished at 1.5 ppm. That document referenced a summary of the petition prepared by Nichino America, Inc., the registrant, which is available in the docket, <https://www.regulations.gov>. One comment was received on the notice of filing. EPA's response to the comment is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has revised one commodity definition and is establishing several tolerances at different levels than requested by the registrant. The reasons for these changes are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. Neither of these exposures are relevant to this action, however. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for isoprothiolane. EPA's assessment of exposures and risks associated with isoprothiolane follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The primary target organ for isoprothiolane is the liver in rats and mice. Consistent decreases in body weight were also observed at the same or lower doses than the liver effects throughout the database. Adverse liver effects included increases in liver enzymes, increased liver weight (absolute and relative), hepatocellular hypertrophy, eosinophilic foci of cellular alterations, eosinophilic cytoplasmic inclusions, and spongiosis hepatis in rats. In mice, following chronic dosing, amyloidosis was observed across several organs at the highest-tested dose. There is no evidence of increased qualitative or quantitative susceptibility in the rat and rabbit developmental toxicity studies or the 2-generation rat reproduction study.

There was no evidence of immunotoxicity, or neurotoxicity observed in any species in the submitted toxicity database.

Isoprothiolane is classified as “Suggestive Evidence of Carcinogenic Potential” based upon increases of skin keratoacanthomas and keratoacanthomas, papillomas, basal cell epitheliomas and/or squamous cell carcinomas combined in male rats. Isoprothiolane is not considered to be genotoxic. The Agency has determined that quantification of risk using a non-linear approach (i.e., chronic reference dose (cRfD)) will adequately account for all chronic toxicity, including any potential carcinogenicity, that could result from exposure to isoprothiolane.

Specific information on the studies received and the nature of the adverse effects caused by isoprothiolane as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies

can be found at <https://www.regulations.gov> in document Isoprothiolane. Human Health Risk Assessment for Isoprothiolane Tolerances for Banana and Rice without a U.S. Registration (First Food Use) hereinafter “Isoprothiolane Human Health Risk Assessment” at pages 23-44 in docket ID number EPA-HQ-OPP-2020-0424.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <https://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticide>.

A summary of the toxicological endpoints for isoprothiolane used for human risk assessment can be found in the Isoprothiolane Human Health Risk Assessment.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to isoprothiolane, EPA considered exposure under the petitioned-for tolerances. EPA assessed dietary exposures from isoprothiolane in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicological studies for isoprothiolane; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the 2003-2008 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA assumed tolerance-level residues or tolerance level residues adjusted to account for the residue of concern for risk assessment; default and empirical processing factors; and 100 percent crop treated (PCT).

iii. *Cancer.* EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. Cancer risk is quantified using a linear or nonlinear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or nonlinear approach is used and a cancer RfD is calculated based on an earlier noncancer key event. If carcinogenic mode of action data are not available, or if the mode of action data determines a mutagenic mode of action, a default linear cancer slope factor approach is utilized. Based on its review of available data, EPA has concluded that a nonlinear RfD approach will adequately account for all chronic toxicity, including any potential carcinogenicity, that could result from exposure to isoprothiolane. Cancer risk was assessed using the same exposure estimates as discussed in Unit III.C.1.ii., *chronic exposure*.

iv. *Percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for isoprothiolane. Tolerance level residues and/or 100% CT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* Residues are not expected in drinking water as the products will not be used in the U.S.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Isoprothiolane is not registered for any use patterns; therefore, there is no residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to isoprothiolane and any other substances and isoprothiolane does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that isoprothiolane has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/pesticide-cumulative-risk-assessment-framework>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the

FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There is no evidence of increased qualitative or quantitative susceptibility in the rat and rabbit developmental toxicity studies or the 2-generation rat reproduction study. In the rat developmental study, developmental effects (decrease fetal weights, increased incidence of small fetuses, and increased incidence of a skeletal variation (unossification of thoracic vertebral body)) were observed in the presence of maternal toxicity (decreased maternal body weight). In the rabbit developmental toxicity study, no significant developmental or maternal effects were seen. In the 2-generation reproductive toxicity study in rats, parental toxicity was manifested as decreases in body weights and food consumption in P and F1 parents; increases in liver weights and spleen weights (P and F1 parents); decreases in thymus weights (P and F1 females); and increased incidences of microscopic findings in the liver (centrilobular hepatic hypertrophy), thymus (thymic atrophy) of P and F1 females. Offspring toxicity (decreased body weights and delayed physical development (delayed eye opening)) and reproductive toxicity (decreased ovary and uterus weights, atrophy of the endometrium and myometrium in the uterus, and atrophy of the ovaries) were observed in the presence of parental toxicity.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

- i. The toxicity database for isoprothiolane is complete at this time.
- ii. Although acute (ACN) and subchronic (SCN) neurotoxicity studies were not available, neurobehavior (functional observation battery (FOB) and motor activity) was assessed in two 13-week oral studies in rats and mice on isoprothiolane; no changes in FOB and motor activity were observed. There was no evidence of neurotoxicity in the isoprothiolane database including

subchronic studies or in the routine clinical observations of the chronic studies. EPA's Hazard and Science Policy Council recommended waiving the acute and subchronic neurotoxicity studies at this time. There is no indication that isoprothiolane is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that isoprothiolane results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. Tolerance-level residues or adjusted tolerance level residues (adjusted to account for the residue of concern), were used for the commodities. An assumption of 100% crop treated was also used for the chronic dietary analysis. There are no residual uncertainties in the exposure database. The residue database is adequate. The Human Health Risk Assessment will not underestimate the exposure and risks posed by isoprothiolane.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, isoprothiolane is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to isoprothiolane from food and water will utilize 5.8% of the cPAD for all infants (<1 year old), the population group receiving the greatest exposure. There are no residential uses for isoprothiolane.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because isoprothiolane is not registered in the United States, the only exposures will be dietary, from residues in or on imported rice commodities or banana; therefore, no short-term or intermediate-term residential exposure is expected.

Because there is no short- or intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short- or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short or intermediate-term risk for isoprothiolane.

4. *Aggregate cancer risk for U.S. population.* As stated in Unit III.A., EPA has concluded that the chronic reference dose will adequately account for all repeated exposure/chronic toxicity, including carcinogenicity, that could result from exposure to isoprothiolane. Based on the lack of chronic risk at regulated levels of exposure, EPA concludes that isoprothiolane will not pose an aggregate cancer risk.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to isoprothiolane residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology 88449-M is available to enforce the tolerance expression in/on banana. Method No. 88449-M includes analysis by liquid chromatography with tandem mass spectroscopy (LC/MS/MS). For rice, the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) review indicated that the QuEChERS (quick, easy, cheap, effective, rugged, and safe) method is adequate for the determination of isoprothiolane.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has established MRLs for isoprothiolane in or on rice, husked at 6 ppm and rice, polished at 1.5 ppm. These MRLs are the same as the tolerances established for isoprothiolane in the United States. There are currently no Codex MRLs for banana or rice, bran.

C. Response to Comments

EPA received one comment in response to the December 21, 2020 Notice of Filing, which recommended that the use of pesticides on food should be banned. Although the Agency recognizes that some individuals believe that pesticides should be banned on agricultural crops,

the existing legal framework provided by section 408 of the FFDCA authorizes EPA to establish tolerances when it determines that the tolerance is safe. Upon consideration of the validity, completeness, and reliability of the available data as well as other factors the FFDCA requires EPA to consider, EPA has determined that the quizalofop ethyl tolerances are safe. The commenter has provided no information indicating that a safety determination cannot be supported.

D. Revisions to Petitioned-For Tolerances

EPA is establishing two tolerances at different levels than requested by the petitioner. Specifically, EPA is establishing the tolerance for banana at 0.9 ppm rather than 1 based on the Organization for Economic Co-operation and Development (OECD) tolerance calculation procedure. The proposed “rice, bran” tolerance was 30 ppm. EPA is establishing the “rice, bran” tolerance at 15 ppm rather than 30 ppm based on the field trial and processing data. In addition, EPA revised the commodity definition from the proposed “rice, polished” to “rice, polished rice” to conform to current practices.

V. Conclusion

Therefore, tolerances are established for residues of isoprothiolane, including its metabolites and degradates, as determined by measuring only isoprothiolane (bis(1-methylethyl) 2-(1,3-dithiolan-2-ylidene)propanedioate), in or on banana at 0.9 ppm; rice, bran, at 15 ppm; rice, husked, at 6 ppm; and rice, polished rice at 1.5 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use”

(66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the *Federal Register*. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 23, 2021.

Edward Messina,

Director, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180--TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Add § 180.721 to subpart C to read as follows:

§ 180.721 Isoprotiolane; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide isoprotiolane, including its metabolites and degradates, in or on the commodities in Table 1 to this paragraph

(a). Compliance with the tolerance levels specified in Table 1 to this paragraph (a) is to be determined by measuring only residues of isoprotiolane (bis(1-methylethyl) 2-(1,3-dithiolan-2-ylidene)propanedioate) in or on the commodities:

Table 1 to Paragraph (a)

Commodity	Parts per million
Banana ¹	0.9
Rice, bran ¹	15
Rice, husked ¹	6
Rice, polished rice ¹	1.5

¹There are no U.S. registrations as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

(b) – (d) [Reserved]

[FR Doc. 2021-26369 Filed: 12/3/2021 8:45 am; Publication Date: 12/6/2021]